Remarks

Claims 95-118 are pending. Claims 106-118 have been withdrawn from consideration, and claims 95-105 stand rejected. Applicants have amended claim 95, and the amendment does not introduce any new matter.

Information Disclosure Statement (IDS)

Applicants note with appreciation that the Examiner has returned signed copies of the IDSs submitted on May 2, 2005 and March 16, 2005. Applicants further note that, based on the telephonic interview with the Examiner, the European Search Report cited in the IDS submitted on May 2, 2005 is appropriate for publication on the face of the patent.

Rejections Under 35 USC § 112, first paragraph

Claims 95-105 stand rejected for allegedly failing to satisfy the enablement and the written description requirements. With respect to both written description and enablement, the Examiner argues that because the term "pleiotrophin" refers to a variety of proteins, including human pleiotrophin and homologs from other organism, the specification does not provide adequate written description for the set of polypeptides that bind to all of the various "pleiotrophin" molecules.

Applicants disagree with the Examiner's assertion that the specification does not provide adequate enablement or written description for the claims. Nonetheless, in order to expedite prosecution, and not in acquiescence to the rejection, Claim 95 and, therefore, its dependent claims 96-105, are amended. Claim 95 as amended recites a polypeptide comprising a definite portion (amino acids positions 368 to 447) of a definite sequence encoded by GenBank Accession No. U66559. Applicants have also amended claim 95 to recite "human pleiotrophin", thereby providing a clear functional characteristic of the claimed polypeptides. In view of the amendments, one of ordinary skill in the art, after reading the specification, is enabled to make and use polypeptides described in such particularity. Similarly, the specification has provided adequate disclosure of the claimed polypeptides such that a skilled artisan can recognize that the inventors, at the time the application was filed, had possession of the claimed invention.

Accordingly, Applicants reconsideration and withdrawal of the rejections under 35 U.S.C. §112, first paragraph.

Rejections Under 35 U.S.C. § 112, second paragraph

Claims 95-105 also stand rejected for alleged indefiniteness.

Claim 95 has been amended to recite ". . . (ALK) as encoded by GenBank accession number U66559 . . . ." Applicants respectfully submit that the amendment has overcome the rejection against claim 95.

With respect to claim 103, Applicants draw the Examiner's attention to page 15, lines 5-7 of the specification as filed, which provides guidance as to what the term "therapeutically effective amount" means. Accordingly, this phrase is not unclear or indefinite.

With respect to claim 105, Applicants respectfully submit that the metes and bounds of the claim do not relate to what the "test substance" is, but are clearly defined by the polypeptide recited therein through dependency from claim 101, which depend from claims 95, 97, or 98. It is expected that any test substance reasonably selected by one of ordinary skill in the art may be used in the subject methods. Applicants note that mere breadth of terminology does not itself give rise to indefiniteness.

Accordingly, Applicants request reconsideration and withdrawal of the rejections under 35 U.S.C. §112, second paragraph.

Rejections Under 35 U.S.C. § 102(b)

Claims 95-99, 101, and 104 stand rejected as allegedly being anticipated by Aigner et al., and claims 95-98 stand rejected as allegedly being anticipated by Morris et al.

Applicants traverse the rejection. Claim 95 and its dependent claims recite a polypeptide comprising the portion of amino acid positions 368-447 of the ALK protein as encoded by GenBank accession number U66559. A cited document cannot anticipate a claim unless the document explicitly or implicitly sets forth all of the elements of the claim in question. Aigner et al. and Morris et al. do not meet this standard for anticipation.

With respect to Aigner et al., the Examiner has acknowledged that Aigner et al. do not teach the sequence or even the name of a polypeptide that might anticipate the claimed polypeptide. Therefore, Aigner et al. do not teach all elements of the pending claims. Further, although Aigner et al. teach a method of panning for the receptor for PTN and a candidate receptor fragment identified by the panning, Aigner et al. do not teach that the candidate receptor fragment is a fragment of ALK, and nor would the practice of the general methodology described in Aigner et al. lead one of ordinary skill in the art to necessarily identify ALK as a PTN-binding protein. The method of screening a phage display library, which is described in only the barest generalities in Aigner et al., does not reveal which protein will be found. In fact there are several different strong binders for PTN known from the literature: RTP-beta/zeta, syndecan, glycosaminoglycans such as heparin and serum albumin. Thus, the method of phage display screening with PTN as a bait will not reveal the ALK receptor described in the invention but a fairly large series of different proteins binding to PTN. Applicants respectfully remind the Examiner that inherency is not a matter of probabilities. A rejection based on inherency is appropriate only when the teachings in the art lead inevitably to the claimed subject matter. Accordingly, Aigner et al. do not, expressly or inherently, anticipate the pending claims.

Morris et al. teach the extracellular domain of an ALK protein as amino acids 27-1030 with amino acids 1-26 being a signal peptide domain and do not teach any ligand binding domain or fragment of the extracellular domain. Applicants note that, because the signal peptide is removed in the membrane insertion process, an extracellular domain of ALK generally does not include such sequences. Therefore, Morris et al. teach the entire extracellular domain of the mature ALK protein, instead of a particular portion of the extracellular domain of the ALK protein comprising amino acid positions 368-447, as required by the pending claims. Therefore, Morris et al. do not anticipate pending claims.

Accordingly, Applicants request reconsideration and withdrawal of the rejections under 35 U.S.C. §102(b).

Rejections Under 35 U.S.C. § 103

Claims 95 and 100-102 stand rejected as allegedly being obvious in view of Aigner et al. or Morris et al. combined with certain other references.

As discussed above, neither Aigner et al. nor Morris et al. teach or suggest the particular portion of an ALK protein as recited in the pending claims. The secondary references do not make up for this deficiency in Aigner et al. or Morris et al. Although Morris et al. teach the extracellular domain of an ALK protein, nothing in Morris et al. or in the cited references would have motivated one of ordinary skill in the art to use the entire extracellular domain as described in Morris et al. to arrive at the claimed polypeptides comprising a particular portion of the extracellular domain of an ALK protein. Accordingly, Applicants respectfully submit that the pending claims are patentable over these cited references and request reconsideration and withdrawal of the rejections.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants submit that the pending claims are in condition for allowance. Early and favorable reconsideration is respectfully solicited. The Examiner may address any questions raised by this submission to the undersigned at 617-951-7000. A three-month petition for extension of time and payment of the required fee are enclosed herewith. Please charge any further fees or credit any overpayments to our Deposit Account No. 18-1945 from which the undersigned is authorized to draw, under order no. 102728-P01-004.

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Respectfully submitted,

By _____
Xuqiong Wu, Ph.D.
Registration No.: 55,745
FISH & NEAVE IP GROUP
ROPES & GRAY LLP
One International Place
Boston, Massachusetts 02110-2624
(617) 951-7000
(617) 951-7050 (Fax)
Attorneys/Agents For Applicant